

Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 1-27 and 29-36 stand rejected as indefinite. The Examiner asserts that claim 1 is indefinite because claim 1 recites in the preamble a limitation that is not recited in any of the process steps and therefore, according to the examiner, the metes and bounds of the claims are unclear.

While applicants respectfully disagree with the Examiner's assertion that these claims are unclear, and the Examiner's reasoning behind the assertion, claims 1, 25 and 26 have been amended to recite a method of surveillance for the presence of a chemical, biological, or radiological agent. These claims each recite assaying the sample for the presence of a chemical, biological, or radiological agent in the body of the claim.

Claim 1 has also been amended to specify that the materials are collected in a pre-existing operation, otherwise unrelated to surveillance. A person of ordinary skill in the art would understand that the pre-existing operation's initial function (e.g. street sweeping) is unrelated to surveillance (see page 8, lines 12-15 of the application as filed); the utilization of such infrastructure in the method of the present invention is obviously for the surveillance for a chemical, biological, or radiological agent. Applicants request that the rejection be withdrawn.

Claim 6-9 is vague and indefinite. The Examiner states that it is unclear what is meant by the limitation "wherein the sample is derived from a street sweeper machine" in claim 6.

Applicants respectfully disagree that this limitation is unclear. A sample derived from a street sweeper is just that: it is a sample that is obtained from or was formerly in association with a street sweeper. The Examiner states that it is unclear if the sample is (a) obtained from a street sweeper machine, (b) taken from the sample domain to the test facility in a street sweeper machine, or if the sample include (c) components of the street sweeper. One of ordinary skill in the art would understand that (a) and (c) are samples derived from a street sweeper machine. Another example of a sample derived from a street sweeper machine is a sample is derived from rinsing collection bins

that collect refuse from a street sweeping machine. Also, one of ordinary skill in the art would understand that a sample that is merely *transported* to a test facility in a street sweeper machine, yet obtained from some other source not in association with a street sweeping machine, is not derived from a street sweeper machine.

Claim 4 stands rejected as vague and indefinite. The Examiner states that there is no active process that uses *Tetrahymena*, and that is unclear how the introduction of *Tetrahymena* further limits the claim. Claim 4 has been amended to recite the active step of "introducing *Tetrahymena pyriformis* to the sample, and assaying for *Bacillus anthracis*". As noted on page 15, line 15 of the application, *Tetrahymena pyriformis* bioencapsulates *Bacillus* spores, and hence concentrates and aids in the detection of *Bacillus* species (e.g. *Bacillus anthracis*).

Claim 17-21 and 29-36 stand rejected as indefinite. The Examiner states that there is no active process step that uses the *Tetrahymena* to assay for the biological agent and that is unclear how the introduction of *Tetrahymena* further limits the claim. Applicants notes that claims 17 and 29 recite "introducing *Tetrahymena pyriformis* to the sample". The addition of *Tetrahymena* to the sample bioencapsulates *Bacillus* spores, and hence concentrates and aids in the detection of *Bacillus* species (e.g. *Bacillus anthracis*).

Claims 32-36 stand rejected as indefinite. The Examiner states that claims 32, 34 and 35 require introducing the sample to a first or second membrane at a temperature effective to kill vegetative bacteria. The Examiner states that it is unclear how this results in identification of bacillus spores by addition of *Tetrahymena*.

Vegetative bacteria are also consumed by *Tetrahymena pyriformis*. Consumption of vegetative bacteria may dilute the concentration of *Bacillus* species within the *Tetrahymena pyriformis* and make detection more difficult (see page 16, lines 5-19).

In view of the remarks above, applicants request that the indefiniteness rejection be withdrawn.

Rejections Under 35 U.S.C. § 102

Claims 1-3, 11-16 and 22-27 stand rejected as anticipated by Cordery et al. (U.S. Pat. No. 6,613,571). Cordery discloses a mail receptacle for collecting air samples.

Claim 1 has been amended to recite that the sample domain is a route undertaken by a street sweeper machine. The Examiner states:

Incoming mail can be collected from mailboxes situated on public streets . . . therefore the mail is collected by Cordery et al. is from a route undertaken by a street sweeper machine . . .

Cordery does not expressly teach a sample domain that is "a route undertaken by a street sweeper machine". Also, the mere possibility that mail *may* be collected from a public street, which in turn *may* be in close proximity to a route undertaken by a street sweeper machine is not sufficient to inherently teach this limitation. See *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991) (inherency cannot be established by probabilities or possibilities). There are many mail collection locations that do not include routes undertaken by a street sweeper machine (e.g. rural areas), and there are many areas in which street sweeper machines operate that are not served by the Postal Service (e.g. smaller or modified versions of street sweepers that are used within buildings).

Since Cordery does not disclose every limitation of claim 1, or claims 3-24 which depend therefrom, applicants request that this rejection be withdrawn.

Claims 25 and 26 call for a sample that "comprises debris or fluids that result from rising an instrumentality used in a collection of materials from a sample domain". The mail in Cordery is not rinsed. Accordingly, Cordery does not disclose this limitation and does not anticipate claims 25, 26 or claim 27 (which depends on claim 26).

Claims 1, 12-13, 15-17, 19-21, 29 and 31 stand rejected as anticipated by Manasherob (App. Envir. Microbio. 1998, 64:1750-1758). Manasherob discusses the bioencapsulation of *Bacillus thuringiensis* inside *Tetrahymena* protozoa. The fate of the *Bacillus thuringiensis* inside the food vacuoles was ascertained in a controlled experiment.

Claim 1 has been amended to recite that the sample domain is a route undertaken by a street sweeper machine. Claims 3-24 depend therefrom. Applicants request that the rejection of claims 12-13, 15-17, 19-21 be withdrawn.

Claim 29 has been amended to incorporate the limitation of claim 30 (which was not rejected) and claim 31 has been canceled. Accordingly the rejection of these claims is now moot.

Claims 1-3, 5-16 and 22-27 stand rejected as anticipated by Hoffmaster (Emerging Inf. Diseases, 2002, Vol. 8, No. 10, supplement 1-12). Hoffmaster discloses a evaluation of real-time PCR performance in assays for *Bacillus anthracis*. The Examiner states that a wide variety of samples were tested including vacuum cleaner debris.

An important aspect of the presently claimed process is the discovery that existing infrastructure (such as a street sweeping operation) can be utilized in the collection of samples to be assayed for the presence of biological, chemical and radiological agents. Claim 1 requires that the "materials are collected in a pre-existing operation, otherwise unrelated to surveillance."

Hoffmaster obtains environmental specimens during the course of an already confirmed outbreak:

The performance of the LRN PCR assay was compared to that of traditional culture methods by testing environmental specimens collected from throughout the United states **during the course of the outbreak.**

Accordingly, the samples for assay obtained in Hoffmaster were not "collected in a pre-existing operation, otherwise unrelated to surveillance". Hoffmaster cannot be read to suggest that the collection techniques disclosed therein (mostly surface swabs) were part of a pre-existing operation, or that they were collected for any reason other than to obtain and assay for Anthrax.

As the limitation "collected in a pre-existing operation, otherwise unrelated to surveillance" is not disclosed in Hoffmaster, applicants request that the anticipation rejection for claims 1-3, 5-16 and 23-24 be withdrawn.

Claim 25 has been amended to call for isolating a sample, which sample comprises debris or fluids that result from rinsing collection bins used to collect materials from a sample domain. Hoffmaster refers to eluting elution of swab specimens, but does not disclose or suggest a sample that includes debris or fluids that result from rinsing collection bins used to collect materials from a sample domain. While the vacuum cleaner in Hoffmaster is used to collect debris specifically for the Anthrax assay, there is no disclosure of rinsing a collection bin associated with the vacuum cleaner. Accordingly, Applicants request that the anticipation rejection of claim 25 over Hoffmaster be withdrawn.

Claim 26 recites a sample domain that includes a collection of materials on a regular, systematic basis through a predetermined, traceable route, the predetermined traceable route converging on a centralized location. As noted above, the collection of environmental samples in Hoffmaster was solely in response to an Anthrax outbreak. Hoffmaster does not teach or suggest the collection of materials on a regular, systematic basis nor does it disclose that the collection is through a predetermined, traceable route, the predetermined traceable route converging on a centralized location. Accordingly, applicants request that the anticipation rejection of claims 26-27 be withdrawn.

In view of the above amendments and remarks, applicants submit that this application is in condition for allowance. If there are any other issues remaining, which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

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